

From: Chen, Xi
Sent: Mon, 9 Sep 2019 19:53:05 +0000
To: Colledge, Michelle (ATSDR/DCHI/CB); Weinstock, Lewis
Cc: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB)
Subject: RE: Ethylene Oxide Sampling at Viant Medical

Just in case you need to cite for reference, here is a link to ERG's 2019 QAPP:

<https://www3.epa.gov/ttn/amtic/files/ambient/airtox/NATTS-UATMP-PAMS-SNOC-Analytical-Support-QAPP-2019.pdf>

On the last page, you will find their 2019 lab EtO MDL.

From: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Sent: Monday, September 09, 2019 3:48 PM
To: Chen, Xi <Chen.Xi@epa.gov>; Weinstock, Lewis <Weinstock.Lewis@epa.gov>
Cc: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>
Subject: Re: Ethylene Oxide Sampling at Viant Medical

Thank you for the information!

Michelle A. Colledge MPH, PhD
CAPT, U.S. Public Health Service
Agency for Toxic Substances and Disease Registry/NCEH/CDC, Region 5
77 W. Jackson Blvd., Room 413
Mailstop ATSD-4J
Chicago, Illinois 60604

Email: mcolledge@cdc.gov
Tel: 312-886-1462
Fax: 312-886-6066



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From: Chen, Xi <Chen.Xi@epa.gov>
Sent: Monday, September 9, 2019 2:39 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>; Weinstock, Lewis <Weinstock.Lewis@epa.gov>
Cc: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>
Subject: RE: Ethylene Oxide Sampling at Viant Medical

Hi Michelle,

ERG is required to determine their MDLs annually and if they have several GC/MS systems, they will report the highest MDL as their lab MDL for an analyte. So what you are reading are actually their EtO lab MDL for 2018(0.082ug/m3) and 2019(0.11 ug/m3). As Lew mentioned, now ERG has three GC/MS systems set up for EtO with individual MDLs from 0.045ug/m3 to 0.11 ug/m3, but their EtO lab MDL will be 0.11ug/m3, the highest among their three systems. I hope this will help. Let me know if you have any other questions.

Thanks,
Doris

From: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Sent: Monday, September 09, 2019 3:28 PM
To: Weinstock, Lewis <Weinstock.Lewis@epa.gov>
Cc: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>; Chen, Xi <Chen.Xi@epa.gov>
Subject: Re: Ethylene Oxide Sampling at Viant Medical

OK-thanks so much. I wasn't aware of the other DLs since everything we have seen thus far is 0.082 ug/m3 or slightly lower (but not higher), even the first sampling in May 2018.

Doris-we appreciate you clarifying!

Michelle A. Colledge MPH, PhD
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From: Weinstock, Lewis <Weinstock.Lewis@epa.gov>
Sent: Monday, September 9, 2019 2:24 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Cc: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>; Chen, Xi <Chen.Xi@epa.gov>
Subject: RE: Ethylene Oxide Sampling at Viant Medical

Hi Michelle:

ERG had several older GC/MS systems that were used for EtO work in 2018 and early 2019. The two systems had different MDL's – and the numbers cited below (in ug/m3) look right to me [0.082 ug/m3, 0.11 ug/m3]. They have since purchased and calibrated a newer system and the MDL is now down in the 0.06 ug/m3 range. That system might have been used for the Phase II work at Viant. Techniques evolve and improve with more experience.

On this message, I am copying Doris Chen of our office. She works very closely with ERG and QA's all our data. Doris is the authoritative source here and can correct/embellish anything that I have said above.

Lewis Weinstock | Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research Triangle Park, NC 27711 | Phone: 919-541-3661

From: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Sent: Monday, September 09, 2019 3:13 PM
To: Weinstock, Lewis <Weinstock.Lewis@epa.gov>
Cc: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>
Subject: Fw: Ethylene Oxide Sampling at Viant Medical
Importance: High

Hi Lew-

I need to pick your brain again. We are reviewing reports from other states for the tox profile revision (our tox profile manager is cc'd here).

(b)(5)

(b)(5)


(b)(5)

We are trying to cite this study in our tox profile, and want to make sure the information is accurate.

FYI- here is what is in the state's Phase 1 report:

Overview

The Viant facility in Grand Rapids, Michigan was identified by EPA NATA analysis as having elevated Ethylene Oxide ambient air impacts. Subsequent modeling by AQD showed that the impacts were above the Initial Risk Screening Level (IRSL) (0.0002 $\mu\text{g}/\text{m}^3$) and Secondary Risk Screening Level (SRSL) (0.002 $\mu\text{g}/\text{m}^3$). To ascertain the accuracy of the modeling, AQD conducted a limited monitoring study for Ethylene Oxide in the vicinity of Viant.

Monitoring for Ethylene Oxide was accomplished using the TO-15 SUMMA canister method. EPA's National Contract Laboratory, Eastern Research Group (ERG), performed the analysis. (b)(5) Since the SRSL is lower than the detection limit of the current method for Ethylene Oxide, the monitoring data will have to be carefully interpreted. For example, if a sample result is reported as non-detect, it is possible that the actual level could still be above the SRSL. 

Versus this in the Phase 2 report (2019):

Monitoring for ethylene oxide was accomplished using the TO-15 Summa canister method. The USEPA's National Contract Laboratory, Eastern Research Group (ERG), performed the analysis. (b)(5) Since the SRSL is lower than the detection limit of the current method for ethylene oxide, the monitoring data will have to be carefully interpreted. For example, if a sample result is reported as non-detect, it is possible that the actual level could still be above the SRSL.

I think below Amy is saying (b)(5)
(b)(5) ..we just need to make sure we are citing this properly. Can you confirm the DL for ERG for the Viant sampling? I know you all have reviewed several state QAPPS/results and work closely with ERG on this issue. If someone there is a better contact, can you send us to the correct person? The reports are attached. I have just seen 0.082 ug/m3 from ERG as a DL for every sampling event thus far but have never seen 0.11 ug/m3.

Thanks,
Michelle

Michelle A. Colledge MPH, PhD
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From: Robinson, Amy (EGLE) <ROBINSONA1@michigan.gov>
Sent: Monday, September 9, 2019 1:11 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>; PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>
Subject: RE: Ethylene Oxide Sampling at Viant Medical

Hi Michelle,

ERG did the sample analysis for both studies. The EPA requires laboratories to determine their MDLs yearly. For 2018 the MDL for EtO was 0.0453 ppbv and for 2019 the MDL for EtO was 0.0614 ppbv.

Amy

Amy K. Robinson
Quality Assurance Coordinator
Air Quality Division
Michigan Department of Environment, Great Lakes, and
Energy
517-242-6561 | robinsona1@Michigan.gov
[Follow Us](#) | Michigan.gov/EGLE

From: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Sent: Monday, September 9, 2019 1:54 PM
To: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>; Robinson, Amy (EGLE) <ROBINSONA1@michigan.gov>
Subject: Re: Ethylene Oxide Sampling at Viant Medical

Hi Amy-

Did ERG also analyze the Phase 2 2019 samples? If so, do you know why their detection limit is

(b)(5)

(b)(5)

We want to make sure we understand the nuances when summarizing data from other investigations.

If it's easier for us to followup with ERG directly, please let us know who to contact.

Best,
Michelle

Michelle A. Colledge MPH, PhD
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From: Hoyer, Marion
Sent: Tue, 21 May 2019 18:32:21 +0000
To: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB); Smith, Darcie; Colledge, Michelle (ATSDR/DCHI/CB)
Cc: Chou, Selene (ATSDR/DTHHS/ETB); Cook, Rich; Roney, Nickolette (ATSDR/DTHHS/ETB)
Subject: RE: EtO Profile contacts

Hi Jennifer,

Thanks for your note. That timing might work, but let's stay in touch.

Marion

From: PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>
Sent: Wednesday, May 08, 2019 2:37 PM
To: Hoyer, Marion <hoyer.marion@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>; Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Cc: Chou, Selene (ATSDR/DTHHS/ETB) <cjc3@cdc.gov>; Cook, Rich <Cook.Rich@epa.gov>; Roney, Nickolette (ATSDR/DTHHS/ETB) <nxr6@cdc.gov>
Subject: RE: EtO Profile contacts

Hi Marion,

Thank you for your email. In the old tox profile, we cited an EPA doc from 1980 that cites a study that detected ethylene oxide as a combustion product of hydrocarbon fuels (Hughes 1959). We would love to include the more recent data from your current preliminary testing. The 3rd draft which goes to EPA for review is tentatively scheduled for release in August.

Does this fit in with your testing timeline?

Thank you,

From: Hoyer, Marion <hoyer.marion@epa.gov>
Sent: Tuesday, May 7, 2019 4:25 PM
To: Smith, Darcie <Smith.Darcie@epa.gov>; Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Cc: Chou, Selene (ATSDR/DTHHS/ETB) <cjc3@cdc.gov>; PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>; Cook, Rich <Cook.Rich@epa.gov>
Subject: RE: EtO Profile contacts

Thank you all for being in touch on this!

Can you tell me your timeframe for developing the new tox profile for EtO?

We do not have evidence that EtO is in mobile source exhaust so if the profile needs to be completed soon, we would not want to list mobile sources as known source of EtO.

I'm asking about your timeframe partly because we are conducting some preliminary testing of mobile sources now and we will have information to inform this issue, although timing on when we can get results and the testing out publicly is not yet clear.

Let me know what you think.

Thanks again,
Marion

From: Smith, Darcie
Sent: Tuesday, May 07, 2019 3:47 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>; Hoyer, Marion <hoyer.marion@epa.gov>
Cc: Chou, Selene (ATSDR/DTHHS/ETB) <cjc3@cdc.gov>; PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>
Subject: RE: EtO Profile contacts

Thanks Michelle!

Marion – below and copied are the names of the people at ATSDR who are working on the updated toxicological profile for ethylene oxide. They are your contacts for the mobile source reference we've been discussing.

Thanks,
Darcie

Darcie Smith
U.S. EPA/OAQPS/ATAG
 919.541.2076
 smith.darcie@epa.gov

From: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Sent: Tuesday, May 07, 2019 3:09 PM
To: Smith, Darcie <Smith.Darcie@epa.gov>
Cc: Chou, Selene (ATSDR/DTHHS/ETB) <cjc3@cdc.gov>; PRZYBYLA, Jennifer (ATSDR/DTHHS/ETB) <xgd1@cdc.gov>
Subject: EtO Profile contacts
Importance: High

Hi Darcie-

Below (and cc'd) are the EtO tox profile contacts we discussed today. Jennifer and Selene-EPA has some concerns about (b)(5) and wanted to discuss with you during the early stage of the update process.

Jennifer Przybyla

xgd1@cdc.gov

Selene Chou

cjc3@cdc.gov

Best,
Michelle

Michelle A. Colledge MPH, PhD

CAPT, U.S. Public Health Service

Agency for Toxic Substances and Disease Registry/NCEH/CDC, Region 5

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From: PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA)
Sent: Thu, 30 Sep 2021 20:20:47 +0000
To: Ramasamy, Santhini
Cc: Abadin, Henry (ATSDR/OAD/OIA); Szafran, Brittany (ATSDR/OAD/OIA); Thayer, Kris; White, Paul
Subject: RE: EtO Profile, Comment 11

Hi Santhini,

Monday at 3 pm works for us. I will send the invite.

Thanks

From: Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Sent: Thursday, September 30, 2021 3:43 PM
To: PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA) <xgd1@cdc.gov>
Cc: Abadin, Henry (ATSDR/OAD/OIA) <hga0@cdc.gov>; Szafran, Brittany (ATSDR/OAD/OIA) <rov0@cdc.gov>; Thayer, Kris <thayer.kris@epa.gov>; White, Paul <White.Paul@epa.gov>
Subject: RE: EtO Profile, Comment 11

Hi Jennifer,

Sorry, Tuesday 1:30 pm does not work for me and I see that is not free for Paul.

I have the following slots available and will any of these work at your end for half hour time?

Mon Oct 4: 3-4 pm
Wed Oct 6 2-3 pm
Thurs Oct 7, 9-10 am
Fri Oct 8, 1-2 pm; 3-4 pm

Thanks.

Santhini

From: PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA) <xgd1@cdc.gov>
Sent: Thursday, September 30, 2021 3:33 PM
To: Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Cc: hga0@cdc.gov; Szafran, Brittany (ATSDR/OAD/OIA) <rov0@cdc.gov>; Thayer, Kris <thayer.kris@epa.gov>; White, Paul <White.Paul@epa.gov>
Subject: RE: EtO Profile, Comment 11

Hi Santhini,

I checked our schedules and Tuesday from 1:30 pm to 2:00 pm works. Please send an invite to myself, Brittany, and Henry.

Thank you,

From: Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Sent: Thursday, September 30, 2021 11:15 AM
To: PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA) <xgd1@cdc.gov>
Cc: Abadin, Henry (ATSDR/OAD/OIA) <hga0@cdc.gov>; Szafran, Brittany (ATSDR/OAD/OIA) <rov0@cdc.gov>; Thayer, Kris <thayer.kris@epa.gov>; White, Paul <White.Paul@epa.gov>
Subject: RE: EtO Profile, Comment 11

Hi Jennifer,

Sorry we did not get back to you sooner. Apologies.

Would you be available next week or later to meet with Paul to discuss Comment 11? I can send the invite upon hearing from you, if that helps.

Santhini

From: PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA) <xgd1@cdc.gov>
Sent: Wednesday, September 15, 2021 3:13 PM
To: White, Paul <White.Paul@epa.gov>; Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Cc: hga0@cdc.gov; Szafran, Brittany (ATSDR/OAD/OIA) <rov0@cdc.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: EtO Profile, Comment 11

Thanks for clarifying Paul. Will 1:30 to 2 pm EST on Monday work for you both to discuss your comments?

From: White, Paul <White.Paul@epa.gov>
Sent: Friday, September 10, 2021 1:56 PM
To: Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>; PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA) <xgd1@cdc.gov>
Cc: Abadin, Henry (ATSDR/OAD/OIA) <hga0@cdc.gov>; Szafran, Brittany (ATSDR/OAD/OIA) <rov0@cdc.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: EtO Profile, Comment 11

Hi Jennifer,

Thanks for taking another look at Comment 11.

(b) (5)

(b) (5)

Thanks for your consideration,
Paul White

From: Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Sent: Friday, September 10, 2021 11:46 AM
To: PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA) <xgd1@cdc.gov>
Cc: hga0@cdc.gov; Szafran, Brittany (ATSDR/OAD/OIA) <rov0@cdc.gov>; White, Paul <White.Paul@epa.gov>
Subject: RE: EtO Profile, Comment 11

Appreciate it. Thanks Jennifer (and Henry). I am looping Paul here to see the best time that would work for all of us to discuss next week.

Best,

-**Santhini** (she/her/hers)

Santhini Ramasamy, PhD, MPH, DABT; Regulatory Program Support Coordinator, Center for Public Health and Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Washington DC. Office: 202 564 8328; Cell: (b) (6)
Email: Ramasamy.Santhini@epa.gov

From: PRZYBYLA, Jennifer (ATSDR/OAD/OCHHA) <xgd1@cdc.gov>
Sent: Friday, September 10, 2021 11:42 AM
To: Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Cc: hga0@cdc.gov; Szafran, Brittany (ATSDR/OAD/OIA) <rov0@cdc.gov>
Subject: EtO Profile, Comment 11

Hello Santhini,

Thank you for the comments you provided on the Ethylene Oxide tox profile. Henry forwarded me your email concerning (b)(5). Let me take a look at our response and get back to you to discuss sometime next week.

Have a good weekend,

Jennifer Przybyla, PhD

Epidemiologist

Office of Innovation and Analytics (OIA)

Agency for Toxic Substances and Disease Registry (ATSDR)

Centers for Disease Control and Prevention (CDC)

xgd1@cdc.gov | 404.498.5264 office

ATSDR Agency for Toxic Substances and Disease Registry

Protecting People from Harmful Environmental Exposures

From: Hanley, Jack (ATSDR/OAD/OCHHA)
Sent: Wed, 7 Oct 2020 17:15:45 +0000
To: Davis, Alison
Cc: Koerber, Mike; Abadin, Henry (ATSDR/OAD/OIA); PRZYBYLA, Jennifer (ATSDR/OAD/OIA); Larson, Theodore (ATSDR/OAD/OIA)
Subject: RE: Two questions from EPA-QAQPS and an invitation

Alison,

I spoke to Henry Abadin the Section Chief of the ATSDR Toxicology Section that prepares the ATSDR tox profiles. Henry, Jennifer Przybyla from his staff, and I are available on October 22 at 2 pm to discuss the EtO tox profile and what would be helpful in terms of EPA/air comments. It would be helpful if you could provide us with a small sampling of the types of questions the EPA regional staff may have on the EtO tox profile or the public comment process.

With regards to the status of the cancer incidence study, we are working on obtaining management approval of (b)(5)

(b)(5) After we obtain the internal approvals, I believe we will take you up on your invitation to talk about the cancer incidence study at a EtO regional coordination call.

We look forward to participating on your regional EtO coordination call. Thanks again for the invitation.

Cordially,

Jack

Henry G. Abadin, MSPH
Section Chief, Toxicology Section
Office of Innovation and Analytics
ATSDR

Jennifer Przybyla, PhD
Senior Service Fellow
Toxicology Section
Office of Innovation and Analytics
ATSDR

Jack Hanley, MPH
Acting Section Chief, Central Section
Office of Community Health and Hazard Assessment
ATSDR

From: Davis, Alison <Davis.Alison@epa.gov>
Sent: Wednesday, October 7, 2020 10:22 AM

To: Hanley, Jack (ATSDR/OAD/OCHHA) <jah8@cdc.gov>
Cc: Koerber, Mike <Koerber.Mike@epa.gov>
Subject: Two questions from EPA-QAQPS and an invitation

Hi Jack,

We have seen that the draft Toxicological Profile and ToxFAQs for ethylene oxide are now available for public comment, and we've been getting questions from our Regions about the best way to provide feedback. I was wondering if you – or whomever you think would be appropriate – would join us at one of our upcoming EtO regional coordination calls to talk about the tox profile and what would be most helpful to ATSDR in terms of comments from EPA/air. There is a call at 2 p.m. tomorrow, and another one at 2 p.m. October 22 (given the short notice, this date might be better).

Also, we wanted to check on the status of the cancer incidence study you all have been planning and extend an invitation for you to talk about that on an upcoming EtO Regional Coordination call as well.

Look forward to hearing from you soon.

-Alison Davis

Alison Davis
Senior Advisor for Public Affairs
US EPA, Office of Air Quality Planning & Standards
Research Triangle Park, NC 27711
Desk: 919-541-7587
Mobile: 919-624-0872